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09/743,787

01/06/2004

Alberto Guillermo Suzarte Paz

024273-00001

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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT

PAPER NUMBER

1618

NOTIFICATION DATE

DELIVERY MODE

01/22/2009

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DCIPDocket@arentfox.com  
IPMatters@arentfox.com  
Patent\_Mail@arentfox.com

|                              |                                      |   |  |
|------------------------------|--------------------------------------|---|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>09/743,787 | <b>Applicant(s)</b><br>SUZARTE PAZ ET AL. |  |
|                              | <b>Examiner</b><br>JAMES W. ROGERS   | <b>Art Unit</b><br>1618                   |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 06 November 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 7 and 9-12 is/are pending in the application.
- 4a) Of the above claim(s) 7, 9 and 10 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/06/2008 has been entered.

Applicant's amendments to the claims have been entered.

### ***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 4,740,376), for the reasons set forth in the previous office action filed 01/28/2008.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sa (Drug Development and Industrial Pharmacy, 17(6), 893-900 (1991), for the reasons set forth in the previous office action filed 01/28/2008.

Claim 11-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yang (US 4,740,376) in view of Sa (Drug Development and Industrial Pharmacy, 17(6), 893-900 (1991)), for the reasons set forth in the previous office action filed 01/28/2008.

### ***Response to Arguments***

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Applicant's arguments filed 11/06/2008 have been fully considered but they are not persuasive. Applicants assert that none of the references cited above describe polymers that are as pure as their own claimed polyvinyl acetate. In particular applicants believe one of ordinary skill in the art would understand that by simple heating at 85° C as in Yang would not result in a sufficiently pure polyvinyl acetate. Applicants also argue that Yang does not disclose heating the polymer or producing the polymer under vacuum as in claim 7. In regards to Sa applicants argue that water and monomer impurity would concentrate in the polymer mass due to affinity and the use of a vacuum desiccator would not separate these impurities since the temperature cannot be raised or else the particles would agglomerate. Applicants lastly state that Sa does not disclose an industrial process.

The relevance of these assertions is unclear. Firstly the examiner would like to clarify that the claims are drawn to a method of producing a solid pharmaceutical preparation not a method of producing PVAc, as such the examiner does not have to search for process to produce the PVAc rather the examiner must only search for PVAc that meets all of the claimed limitations for the polymer itself such as MW, Tg and impurity content. As noted before since PVAc was commercially purchased and added as an ingredient to an encapsulation material it would be obvious that by controlling the melt temperature PVAc could essentially be free of water, since it was commercially available and was further processed by melt with the other ingredients of the composition. It is further noted by the examiner that since the claim is drawn to a method of producing a composition which can be a solution, applicants have not

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excluded that this solution could be aqueous. Thus whether or not PVAc contains some water would be of little relevance if the substantially water free PVAc is added to a pharmaceutical preparation that can include water. In regards to applicants assertion that the examiner erred in stating that the residual monomer content of PVAc would be as low as currently claimed, it is noted by the examiner that the melt conditions employed by Yang used a temperature of about 85°C, well above the bp of vinyl acetate (VAc) which has a bp of around ~73°C. Thus by the melt processing it would be obvious that essentially any amount of residual monomer VAc present within the commercially bought PVAc would have boiled off during processing. Furthermore as noted in the previous office action since PVAc was commercially bought for both the Yang and Sa references it would be obvious to one of ordinary skill in the art to select a commercially available PVAc which would have low impurity content since the polymer is used in a pharmaceutical formulation. It is considered to be ordinary and routine experimentation by the examiner for one of ordinary skill in the art to purify a polymer to a high degree if it is to be used in a pharmaceutical dosage form since reducing the amount of contaminants and impurities will decrease any toxic side effects. It is further noted by the examiner that applicants arguments are conclusionary in nature in regards to the amounts of water and impurities and applicants have not showed any experimental results in which the PVAc after processing into the pharmaceutical formulations of Yang and Sa that would not have the claimed residual impurities and water content. Also Sa discloses that acidic acid was used to dissolve PVAc and was evaporated off, therefore the examiner assumes the concentration of acetic acid would

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be essentially zero. Regarding applicants assertion that their process is an industrial process and is not restricted to production of microspheres, as currently amended applicants claims do not preclude the use of non-industrial processes to produce the pharmaceutical formulation nor have applicants provided evidence besides conclusionary statements as to why Sa does not teach a process that could be scaled up to an industrial process.

### **Conclusion**

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618